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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,237	01/22/2004	Albrecht Wendel	P61750US1	2027

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
01/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/761,237	Applicant(s) WENDEL ET AL.	
	Examiner Ja-Na Hines	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 December 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *03 December 2007*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *19-22*.
   Claim(s) withdrawn from consideration: *None*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

MARK NAVARRO
PRIMARY EXAMINER

The rejection of claims 19-22 under 35 U.S.C. 112, second paragraph, is maintained. Applicants again argue that the meaning of "standardized blood unit dose" should not be considered indefinite. This argument is not persaussive because the standard is that claims must particularly point out and distinctly claim the subject matter which applicant regards as his invention. The phrase "standardized blood unit dose" in claims is a relative phrase which renders the claim indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no teaching of how the standardization occurs or by whom the standardization is determined. Therefore applicants' definition shows the indefiniteness concerning the meaning of standardized blood unit dose and the rejection is maintained.

The rejection of claims 19-22 under 35 U.S.C. 102(b) as being anticipated by Rubinstein et al., (PNAS, 1995. Vol. 92, pages 10119-10122) is maintained. Applicants' argue that Rubinstein, teach measuring within the frozon sample and the instant invetion measuring is done with the frozen samples. However the claims specifically require that the sample is a thawed unit, Rubenstein and Kaye both teach using as the blood sample a thawed cryopresed unit of whole bllod. Therefore applicants argument is not persaussive.

Applicants argue that Rubinstein discloses further processing beofre use. The fact that Rubinstein et al., further processing is irrelevant, because Rubinstein teach the testing of a material by contacting the material with a blood sample wherein the sample is a thawed cryopreserved unit of whole blood containing a cryopreservative, diluent and clotting inhibitors. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998). Furthermore, the claims allow for additional steps in ivew of the "comprises" language. Therefore the argument is not persaussive.

The rejection of claims 19-21 under 35 U.S.C. 102(b) as being anticipated by Kaye et al., (J. of Virological Methods, 1991. Vol. 35,pages 217-226) is maintained. Applicants argue that Kaye et al., do not teach a method for using whole blood for detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against a material or object, as there is according to the presently claimed invention. However, contrary to applicants' statements, the cryopreservative, Glycigel is contacted with whole blood. Accordingly, the broad interpretation of immunofunctional, toxic, or modulatory blood reaction by any biological, physical, chemical or physiochemical method, the performance of PCR meets the instantly recited limitations. There are no limitations on the types of materials contacted with the blood or on the type of testing performed on the blood. There is not a even a requirement that the detection correlate to the contact of the material or object on the blood. Therefore applicant's argument that contacting the blood with a material and testing the blood thereafter is not persuasive especially when considering the breadth of the claims and the lack of limitations concerning the contact step and detection step; therefore Kaye et al., anticipate claims 19-22.
Applicants aruge that Rubenstein and Kaye relate to fields of therapy and the instant invention relates to fields of diagnosis/measurment. In response to applicant's argument that Rubenstein and Kaye are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, applicant's arguments is not persuasive especially when considering that Rubenstein and Kaye et al., anticipate claims 19-21 of the instant application.